

## **US Federal Register Notice: Drug Pricing Study**

### How do OECD countries set pharmaceutical prices?

In the UK, the prices of branded medicines and the profits that manufacturers are allowed to make on their sales to the National Health Service (NHS) are regulated by the Pharmaceutical Price Regulation Scheme (PPRS). It is a voluntary agreement made between the Department of Health and the branded pharmaceutical industry – represented by the Association of the British Pharmaceutical Industry (ABPI) – under Section 33 of the Health Act 1999.

The PPRS covers all licensed, branded, prescription medicines sold to the NHS. It does not cover products without a brand name (generics) nor branded products available without prescription (over the counter (OTC) medicines) except when prescribed by a doctor. It is a UK wide scheme and covers around 80% by value of the medicines used in the NHS in both primary and secondary care (some £7 billion).

The objectives for the 1999 scheme, as stated in the agreement, are to:

- Secure the provision of safe and effective medicines for the NHS at reasonable prices;
- Promote a strong and profitable pharmaceutical industry capable of such sustained research and development as should lead to the future availability of new and improved medicines;
- Encourage the efficient and competitive development and supply of medicines to pharmaceutical markets in this and other countries.

In summary, the PPRS:

- allows companies freedom of pricing for all new chemical entities
- requires companies to seek the Department's agreement for price increases which are only granted if the reasons for the application meet the criteria for increases set out in the agreement
- requires companies with NHS sales of more than £25 million per year to submit annual data on sales, costs, assets and profitability and to repay the excess where profits exceed the agreed return on capital threshold
- provides significant support for research and development (R&D) and innovation through improved allowances for R&D.

The agreement seeks to achieve reasonable prices for the NHS, whilst recognising that the industry needs to earn the money to enable it to develop and market new and improved medicines.

The scheme does not differentiate between domestic and imported medicines.

A maximum price scheme for the main generic medicines (those without a brand name) used in NHS Primary Care was introduced in August 2000. The Government is currently considering options for the longer-term arrangements for the supply and reimbursement of generic medicines.

Further information on UK price controls for both branded and generic medicines is available at

<http://www.dh.gov.uk/PolicyAndGuidance/MedicinesPharmacyAndIndustry/fs/en>

Within OECD countries, what mechanisms do governments use to control pharmaceutical expenditures?

In the UK, the Government has set up a number of systems to ensure that prescribers have both the *information* and appropriate *incentives* to achieve value for money in their prescribing. Sources of information include the National Institute for Clinical Excellence (NICE), the National Prescribing Centre, and Primary Care Trust (PCT) medical and pharmacy advisers; the incentive structure includes unified PCT allocations, national and local quality incentives, and the new *Payments by results* regime.

GPs are encouraged to prescribe drugs by their generic name to gain best value for money. Rates of generic prescribing are now approaching 80%. Prescribing advisers – these advisers, mainly pharmacists, are employed at various levels in the NHS (Strategic Health Authorities (StHA) and PCT), having a common aim to encourage and secure rational and cost-effective prescribing. There are now more than 1200 advisers, many of whom undertake face to face reviews with GPs and carry out reviews of repeat prescribing etc activity. The Prescribing Support Unit (funded by DH) has produced a number of analytical tools to aid advisers.

If price controls and other government cost control mechanisms were eliminated in OECD countries, how and to what degree would pharmaceutical prices and expenditures change in those countries and in the United States? What effects would these changes have on the sales and profits of pharmaceutical manufacturers?

A study into the extent of competition in the supply of branded medicines to the NHS, which was jointly undertaken by the Department and the ABPI, as part of the 1999 PPRS agreement, was published in 2002. The Department concluded that there was insufficient evidence of price competition for deregulation.

The conclusions of the study are set out below. The full study is available via the Department's web-site.

The supply of branded medicines to the NHS is not a conventional market. The role of the prescriber, the clinical needs of the patient and the responsibility of the Government to fund the cost of medicines as well as the operation of the PPRS are key factors in the operation of the market and of price competition. At the same time competition between branded pharmaceutical companies is not limited to price as they also compete on the basis of efficacy and ease of use. Companies also compete to bring new products to the market as quickly as they can in the patent life. This study looks at the extent of price competition only.

The definition of a 'market' within the context of branded medicines is not straightforward. It is clear that the supply of branded medicines to the NHS does not comprise a single market. Accordingly it is necessary to define markets for branded medicines as those that comprise medicines for the treatment of a specific condition. Within this definition companies with the first entrant may sometimes retain exclusivity in that market for a limited period of time only but this period varies considerably.

Overall the industry is not highly concentrated although some 60% of the therapeutic sub-markets examined by the study have a player with more than 40% market share - the benchmark level of concentration below which the Office of Fair Trading (OFT) considers it unlikely that a company will have a dominant position. This is despite the presence of more than one product in most markets. There is evidence that first entrants retain market share despite the later entry of cheaper products. Equally second entrants out-perform cheaper third entrants. On the demand-side prescribers rate cost below efficacy when making prescribing decisions and it is a matter of debate as whether the awareness of relative prices is high enough to stimulate price competition. It is too early to assess the impact of primary care trusts on prescribing behaviour. Generic prescribing is taking an increasing share of the market and there is some evidence of price competition in parts of the hospital sector.

As acknowledged above, the operation of this market has been affected by the PPRS. However, where price changes have occurred, the study was unable to find consistent volume responses to such changes. Over half of price changes triggered no response from competitors. In the majority of cases, the launch of new products provoked no price response from competitor products.

The Government believes that the abolition of price controls would lead to higher prices. In the US where there is a minimal level of medicine price regulation compared to Europe, medicine list prices increase by 3.5% to 5.5% per annum. That said, the extent of price increases in the UK is not predictable nor is the impact on the US market.

Could OECD countries reduce costs by increasing the use of generic drugs? What steps would the governments need to take to facilitate the use of generic drugs?

In the UK, doctors are encouraged to prescribe rationally and to make the best possible use of NHS resources. It has long been the Department's policy to encourage GPs to prescribe drugs by their generic name, where possible, for reasons of good professional practice and because of the opportunities for more effective use of NHS resources. It is recognised, however, that there are circumstances in which generic prescribing is inappropriate. Decisions on what to prescribe must remain for doctors taking into account full knowledge of patients and their conditions; overriding criteria for prescribing for each patient must continue to be drug effectiveness and suitability.

The UK has a very high rate of prescriptions written generically. In 2003, the share of prescription items written generically (in the community, in England) was almost 78 per cent, accounting for almost 24 per cent of expenditure.

List any additional drug pricing practices by OECD countries that utilize non-tariff barriers.

As pricing mechanisms in the UK do not distinguish between UK based companies and non-UK based companies, we do not consider pricing policy on pharmaceuticals in the UK to be non-tariff barriers.